

**REMARKS/ARGUMENTS**

Claims 1-11 are pending in the instant application. Claims 2 and 9-11 have been withdrawn from consideration by the Examiner, as being drawn to a non-elected invention. Claims 3-6 have been cancelled and claims 1 and 7 have been amended. Claims 1, 4-6 and 8 stand rejected under 35 U.S.C. 112 as being ambiguous. Further, claims 1, 6 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Griswold et al (US Patent no. 5,824, 696). Claims 1, 4-6 and 8 further stand rejected under 35 U.S.C. 103(a) as being unpatentable over Archer (WO 03/006070) in view of Griswold et al.

Applicant has amended the claims by amending claim 1 and claim 7. Claims 4-6 have been cancelled (incorporated in amended claim 1). Reconsideration is respectfully requested.

**35 U.S.C. 112 second paragraph rejections**

Claims 1, 4-6 and 8 stand rejected under 35 U.S.C. 112 as being ambiguous. In response the Applicant has amended claim 1 by:

- Specifying that X1 of formula V is Gly. Basis for this is found on page 8 of the PCT specification.
- Specifying that X2 is Arg, N-alkylated Arg, or ~~a mimetic of Arg~~ Phe[4-guanidino] or Gly-4-piperidyl [N-amidino],

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- Specifying that L is a bond or a linker of formula  $\text{-NH-(CH}_2\text{)}_m\text{-}$  optionally combined with  $\text{---}$

$\text{CO-(CH}_2\text{)}_m\text{-CO-}$  where m denotes a positive integer from 1 to 10. Basis for this is found on page 8 of the PCT specification. As L can be a bond or a linker, the former specification that n of formula (I) was 0 or 1 has been deleted.

- Specifying that Z denotes a chelating agent of formula (VII). Basis for this is found in former claim 4 and on page 11 and 12 of the PCT specification.

- Specifying that M is selected from a group of gamma emitting moieties for Radio or SPECT imaging. Basis is found in former claim 6.

Further:

Claim 5 has been cancelled and the rejections have been overcome.

Claim 6 has been cancelled as the subject matter has been included in claim 1. The language has been amended to "closed language" as requested.

Claim 7 has been amended to specifically list four compounds falling under the formula I of claim 1. The applicant respectfully request that this claim is reconsidered and kept pending as it clearly falls under claim 1 (Group 1 invention).

Based on the above amendments Applicant believes the claims comply with the requirements of 35 U.S.C. 112 and reconsideration is respectfully requested.

**35 U.S.C. 102 Rejections**

Claims 1, 6 and 8 stand rejected under 35 U.S.C 102(b) as being anticipated by Griswold et al (US Patent No. 5,824,696). The rejection is respectfully traversed.

The applicant is aware that several publications exist where angiotensin and derivatives of angiotension, including radiolabelled derivatives are published, as discussed on pages 1 to 5 in the patent specification. Applicant has, however, found that the octapeptide AngII, when substituted in specific positions in the peptide, not only retains its binding capacity but surprisingly increases its affinity for the AngiotensinII receptors, as noted in the 5<sup>th</sup> paragraph of page 5 in the specification.

In claim 1, as amended, the amino acid X1 is replaced with Gly in the definition of V in formula (I). Further, it has been specified that the Z forms a bond with the amino acid Gly, optionally through a linker L. Z denotes a chelating group formula VII, which can carry a gamma emitting moiety for Radio or SPECT imaging selected from a specific group.

Griswold discloses use of an angiotensin II receptor antagonist for the treatment of chronic inflammatory diseases. The specie [<sup>125</sup>I](Saar1, Ile) angiotensin II is disclosed, i.e. an angiotensin II type peptide labelled directly with <sup>125</sup>I is disclosed. Various substitutions of amino acids in the angiotensin II sequence is suggested in the table in column 15 and 16.

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However, Griswold fails to disclose compounds of formula I having a Gly in the first

position. Further, Griswold fails to disclose compounds of formula I comprising a chelating

group of formula VII. Hence, applicant believes claim 1 is novel over Griswold and

respectfully request reconsideration.

### **35 U.S.C. 103 Rejection**

Claims 1, 4-6 and 8 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Archer (WO 03/006070) in view of Griswold et al.

Archer is directed to improved chelator compounds, enclosing chelating agents of similar structures as those of formula VII of claim 1 of the instant application.

There is however no indication by Archer that the chelating agent disclosed should be linked to a peptide having affinity for the angiotensin II type 1 receptor. Further, there is no indication in either of the Archer and Griswold documents that a chelating group should be linked to the peptide by a Gly entity. The skilled person, being aware of Griswold and Archer, would not be encouraged to use the chelating agents of Archer and linking this to a peptide of Griswold, making the necessary substitutions to reach at the pharmaceuticals of claim 1. Hence, the Applicant believes the claims, as amended, are non-obvious and reconsideration is respectfully requested.

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**CONCLUSION**

In view of the amendments and remarks herein, Applicant believes that each ground for rejection made in the present application has been successfully overcome, and that all the pending claims 1, 7, and 8 are in condition for allowance.

The Examiner is invited to telephone the undersigned in order to resolve any issues that might arise and to promote the efficient examination of the current application.

Respectfully submitted,

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